exemptions in subpart D of part 20 of this chapter and to the limitations on exemption in subpart E of part 20 of this chapter.

(b) Any request for confidentiality of the identity of a cosmetic ingredient should contain a full statement, in a well-organized format, of the factual and legal grounds for that request, including all data and other information on which the petitioner relies, as well as representative information known to the petitioner that is unfavorable to the petitioner's position. The statement of the factual grounds should include, but should not be limited to, scientific or technical data, reports, tests, and other relevant information addressing the following factors that FDA will consider in determining whether the identity of an ingredient qualifies as a trade secret:

(1) The extent to which the identity of the ingredient is known outside petitioner's business;

(2) The extent to which the identity of the ingredient is known by employees and others involved in petitioner's business;

(3) The extent of measures taken by the petitioner to guard the secrecy of the information;

(4) The value of the information about the identity of the claimed trade secret ingredient to the petitioner and to its competitors;

(5) The amount of effort or money expended by petitioner in developing the ingredient; and

(6) The ease or difficulty with which the identity of the ingredient could be properly acquired or duplicated by others.

(c) The request for confidentiality should also be accompanied by a statement that the identity of the ingredient for which confidentiality is requested has not previously been published or disclosed to anyone other than as provided in §20.81(a) of this chapter.

(d) FDA will return to the petitioner any request for confidentiality that contains insufficient data to permit a review of the merits of the request. FDA will also advise the petitioner about the additional information that is necessary to enable the agency to proceed with its review of the request.

(e) If, after receiving all of the data that are necessary to make a determination about whether the identity of an ingredient is a trade secret, FDA tentatively decides to deny the request, the agency will inform the person requesting trade secrecy of its tentative determination in writing. FDA will set forth the grounds upon which it relied in making this tentative determination. The petitioner may withdraw the records for which FDA has tentatively denied a request for confidentiality or may submit, within 60 days from the date of receipt of the written notice of the tentative denial, additional relevant information and arguments and request that the agency reconsider its decision in light of both the additional material and the information that it originally submitted.

(f) If the petitioner submits new data in response to FDA's tentative denial of trade secret status, the agency will consider that material together with the information that was submitted initially before making its final determination.

(g) A final determination that an ingredient is not a trade secret within the meaning of §20.61 of this chapter constitutes final agency action that is subject to judicial review under 5 U.S.C. Chapter 7. If suit is brought within 30 calendar days after such a determination, FDA will not disclose the records involved or require that the disputed ingredient or ingredients be disclosed in labeling until the matter is finally determined in the courts. If suit is not brought within 30 calendar days after a final determination that an ingredient is not a trade secret within the meaning of 21 CFR 20.61, and the petitioner does not withdraw the records for which a request for confidentiality has been denied, the records involved will be made a part of FDA files and will be available for public disclosure upon request.

[51 FR 11444, Apr. 3, 1986, as amended at 57 FR 3130, Jan. 28, 1992]

§720.9 Misbranding by reference to filing or to statement number.

The filing of Form FDA 2512 or assignment of a number to the statement does not in any way denote approval by the Food and Drug Administration of

the firm or the product. Any representation in labeling or advertising that creates an impression of official approval because of such filing or such number will be considered misleading.

[57 FR 3130, Jan. 28, 1992]

PART 730—VOLUNTARY FILING OF COSMETIC PRODUCT EXPERIENCES

Sec.

AUTHORITY: Secs. 201, 301, 601, 602, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 361, 362, 371, 374).

SOURCE: 39 FR 10062, Mar. 15, 1974, unless otherwise noted.

§ 730.1 Who should file.

Every person who is a manufacturer, packer, or distributor of a cosmetic product is requested to file a Form FD–2704 (Cosmetic Product Experience Report), with respect to all reportable experiences which have been reported to him concerning any of his cosmetic products in commercial distribution, regardless of whether he is a participant in the voluntary program to register cosmetic product establishments pursuant to part 710 of this chapter, and regardless of whether he is a participant in the voluntary program to file cosmetic product ingredient and raw material composition statements pursuant to part 720 of this chapter. In addition, every person who is a manufacturer, packer, or distributor of a cosmetic product, whether or not he has received any information concerning a reportable experience in regard to any of his cosmetic products in his system of commercial distribution, is requested to file a Form FD–2706 (Summary Report of Cosmetic Product Experience by Product Categories). This request extends to any foreign manufacturer, packer, or distributor of a cosmetic product imported into any State. No filing fee is required.

[39 FR 10062, Mar. 15, 1974, as amended at 46 FR 38073, July 24, 1981]

§ 730.2 Time for filing.

(a) Reportable experiences should be reported on an annual basis, for the period January through December, not later than 60 days after the close of the reporting period.

(b) A summary report of cosmetic product experience by product categories should be filed on an annual basis, for the period January through December, not later than 60 days after the close of the reporting period.

[51 FR 25687, July 16, 1986]

§ 730.3 How and where to file.

Form FDA 2704 (Cosmetic Product Experience Report) and Form FDA 2706 (Summary Report of Cosmetic Product Experience by Product Categories) are obtainable from, and the completed forms should be mailed or delivered to, Cosmetic Product Experience Report, Center for Food Safety and Applied Nutrition (HFS–100), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[51 FR 25687, July 16, 1986, as amended at 61 FR 14481, Apr. 2, 1996]

§ 730.4 Information requested.

(a) Form FD–2704 (Cosmetic Product Experience Report) requests the following information:

(1) The name of the person (manufacturer, packer, or distributor) designated on the label of the cosmetic product.

(2) Time period covered by the report.

(3) The complete name of the cosmetic product exactly as it appears on the label of the product.

(4) The cosmetic product category, as set forth in §720.4(c) of this chapter and on the form, which best describes the product's intended use.

(5) Total number of reportable experiences during this reporting period and number of these experiences requiring professional medical attention.

(6) Total number of product units of the cosmetic product estimated to have been distributed to consumers during this reporting period.